EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE VALSARTAN PRODUCTS LIABILITY LITIGATION	No. 1:19-md-2875-RBK

EXPERT REPORT OF PROFESSOR ZIRUI SONG, MD, PHD IN SUPPORT OF PLAINTIFF'S MOTION FOR CLASS CERTIFICATION

TABLE OF CONTENTS

I. QUALIFICATIONS 1

II. ASSIGNMENT 3

III. PRICING OF HEALTH CARE SERVICES 5

A. Definitions 5

B. Pricing of Medical and Procedural Services in the U.S. Health Care System 8

C. Pricing of Laboratory Services in the U.S. Health Care System 15

D. Variations in Prices Within Insurers 17

IV. COMMON METHODOLOGY FOR ESTIMATING SPENDING ON MEDICAL MONITORING 22

A. Medical Services in a Monitoring Program 22

B. Composition of the Patient Population in Monitoring 25

C. Calculating Spending 26

I. QUALIFICATIONS

1. My name is Zirui Song. I am an Associate Professor of Health Care Policy at Harvard Medical School and an internal medicine physician at Massachusetts General Hospital. I practice outpatient adult primary care and inpatient general medicine on the Department of Medicine's resident teaching service at Massachusetts General Hospital, where I also teach health policy and economics to residents and fellows across specialties. I also serve as a faculty affiliate in the Harvard Medical School Center for Primary Care, where I collaborate with colleagues on policy and research projects that pertain to health care financing and primary care.

2. I received a M.D., Magna Cum Laude, from Harvard Medical School in 2014, a Ph.D. in Health Policy (Economics) from Harvard University in 2012, and a B.A. in Public Health Studies with Honors from Johns Hopkins University in 2006 (with a minor in Economics). I was a pre-doctoral and post-doctoral fellow in Aging and Health Economics at the National Bureau of Economic Research. Clinically, I did residency training in Internal Medicine at Massachusetts General Hospital from 2014 through 2017, during which I worked on different inpatient services (including general medicine, cardiology, intensive care, and oncology), rotated through different subspecialty outpatient clinics (such as dermatology, rheumatology, and clinics for patients who are homeless), and began my primary care practice that I maintain today. I received the Morton N. Swartz, M.D. Humanism in Medicine Award from the Department of Medicine at MGH.

3. I have taught health policy and health economics in undergraduate, Masters-level, and Ph.D.-level courses in the Harvard Graduate School of Arts and Sciences, Harvard T.H. Chan School of Public Health, Harvard Kennedy School, and Harvard Business School. I have also taught classes on health policy and health economics to medical students and clinical trainees (residents and fellows) at Harvard Medical School, Massachusetts General Hospital, and the Brigham and Women's Hospital, along with guest lectures at the University of Pennsylvania. I have co-directed the "Centers of Expertise in Health Policy and Management-Health Policy" course for clinical trainees at Mass General Brigham and the "Evidence, Insight and Strategy for Optimizing Health Benefits" course for U.S. employers in the Harvard Medical School Office

for External Education. This year, I currently co-direct the Harvard Medical School Essentials of the Profession (EOP) Health Policy course for first-year medical and dental students. I also lead the development of a new Health Policy concentration in the Department of Medicine Residency Program at Massachusetts General Hospital.

4. My research in health policy and economics focuses on health care financing, payment, and spending in the U.S. health care system. This work examines the pricing of health care services, policies and market forces that influence spending, and changes in provider behavior associated with changes in payment systems and incentives.[1] I have published approximately 100 peer-reviewed academic research articles, essays, and book chapters (including recent studies on Medicare and commercial pricing of medical services). My research has been recognized by professional organizations such as the AcademyHealth Article-of-the-Year Award in 2013 for the "best and most relevant scientific work in the fields of health services research and health policy," the "Ten Influential Studies in Health Services Research" from the National Academy of Medicine, and the 2020 Health Care Research Award from the National Institute for Health Care Management Foundation. I have been honored to receive the 2016 Seema S. Sonnad Emerging Leader in Managed Care Research Award from the *American Journal of Managed Care*, Bernie J. O'Brien New Investigator Award from the International Society for Pharmacoeconomics and Outcomes Research, and 2020 Outstanding Junior Investigator of the Year from the Society of General Internal Medicine. I also serve on the editorial board of *PLOS Medicine*.

[1] See, for example: Z. Song, *et al.,* "Changes in Health Care Spending and Quality 4 Years into Global Payment," *New England Journal of Medicine*, 371(18), 2014, pp. 1704-1714; Z. Song, *et al*., "Health Care Spending, Utilization, and Quality 8 Years into Global Payment," *New England Journal of Medicine*, 381(3), 2019, pp. 252-263; Z. Song, *et al*., "Lower-Versus Higher-Income Populations in the Alternative Quality Contract: Improved Quality and Similar Spending," *Health Affairs*, 36(1), 2017, pp. 74-82; D. Haas, *et al.*, "Evaluation of Economic and Clinical Outcomes Under Centers for Medicare & Medicaid Services Mandatory Bundled Payments for Joint Replacements," *JAMA Internal Medicine*, 179(7), 2019, pp. 924-931; Z. Song, "The Pricing of Care Under Medicare for All: Implications and Policy Choices," *Journal of the American Medical Association*, 322(5), 2019, pp. 395-396; Z. Song, *et al*., "Out-Of-Network Spending Mostly Declined in Privately Insured Populations With A Few Notable Exceptions From 2008 To 2016," *Health Affairs*, 39(6), 2020, pp. 1032-1041; Z. Song and D.A. Chokshi, "The Role of Private Payers in Payment Reform," *Journal of the American Medical Association*, 313(1), 2015, pp. 25-26; Z. Song, T. Lillehaugen, and J. Wallace, "Out-of-Network Laboratory Test Spending, Utilization, and Prices in the US," *Journal of the American Medical Association*, 325(16), 2021, pp. 1674-1676.

5. I have worked on federal payment policy at the U.S. Department of Health and Human Services concerning payments to private insurers in the Medicare Advantage program. This work helped motivate several subsequent academic papers that also pertain to the differences in prices of health care services in the U.S. across public and private insurers.[2] I have served as a Visiting Fellow in the Massachusetts Health Policy Commission and on the Massachusetts Medical Society Task Force on Health Care Reform. I have also served on Technical Expert Panels for the U.S. Department of Health and Human Services and the Health Care Cost Institute.

6. A more detailed description of my qualifications is provided in my Curriculum Vitae, in Attachment A. Attachment B lists the materials I relied upon for this report. I am compensated for this matter at an hourly rate. This compensation is not contingent upon the outcome of this matter. The opinions I state in this report are stated within a reasonable degree of professional certainty. My analysis of the issues at hand is ongoing. I reserve the right to respond to, rebut, opine on, or incorporate opinions offered by other experts in these matters. I reserve the right to modify or supplement this report based on new materials or testimony that may become available to me, including, but not limited to, other expert witness reports.

II. ASSIGNMENT

7. In this matter, the complaint alleges that, since September 2012, Defendants have marketed and sold valsartan-containing drugs (VCDs) that were "contaminated with unintended nitrosamine impurities" of N-nitrosodimethylamine ("NDMA") and/or N-nitrosodiethylamine ("NDEA") and therefore "nonmerchantable."[3] Defendants allegedly misrepresented to consumers that these generic VCDs were safe and bioequivalent to their brand counterparts, even though they were not and "willfully ignored deficiencies and warning signs regarding the

[2] Z. Song, "Using Medicare prices—Toward Equity and Affordability in the ACA Marketplace," *New England Journal of Medicine*, 377(24), 2017, pp. 2309-2311; Z. Song and S. Basu, "Improving Affordability and Equity in Medicare Advantage," *Inquiry*, 56, 2019, pp. 1-7; Z. Song, "Making the Affordable Care Act Marketplace More Affordable," *JAMA Health Forum*, 2(5), 2021, pp. 1-3.

[3] See Consolidated Third Amended Medical Monitoring Class Action Complaint, in this matter, filed November 1, 2021 (hereafter "Complaint"), pp. 2-4.

operating standards and manufacturing and testing conditions" in some of their manufacturing plants.[4] The complaint contends that Defendants' conduct exposed Plaintiffs to "highly dangerous and potentially fatal carcinogenic substances" and therefore Defendants should "fund medical monitoring" and (among other things) pay Plaintiffs "compensatory damages necessary for their monitoring and care."[5] The medical monitoring class is defined as all persons who consumed the Defendants VCDs containing NDMA or NDEA, and who accumulated sufficient quantities of lifetime cumulative exposure to require medical monitoring given the increased risk of cellular and genetic injury leading to an increased risk of cancer.

8. A major question has emerged in this setting. Given the need for medical monitoring of individuals who have consumed NDMA or NDEA through the pharmaceutical agents in this case, is there a common methodology for determining the potential health care **spending** accrued from the medical monitoring of these individuals given their increased risk of cancer?

9. As detailed below, this report begins by providing an overview of the pricing of health care services in the U.S., including a definition of key terminology, a description of the Current Procedural Terminology (CPT) coding system, and an explanation of how the prices of health care services are determined—both in public health insurance programs (notably the federal Medicare program) and in the commercial health insurance sector (Section III). Specifically, it explains how physician fees are calculated using relative value units, which are multiplied by a conversion factor to derive final prices in U.S. dollar terms, and why prices can differ based on not only the insurer, but also the site of care and the in-network or out-of-network status of the health care provider with respect to a person's health insurance plan. Next, the report describes a common methodology for estimating health care spending associated with a medical monitoring program (Section IV). It provides several examples of services that could plausibly be included in a monitoring program to illustrate how the common methodology would work. Finally, the

[4] Complaint, pp. 3-4.

[5] Complaint, pp. 5 and 230-231.

report briefly addresses how spending on medical monitoring could be determined for the class of patients.

10. For the sake of clarity, I am opining about the medical services (medical benefits) for the medical monitoring class members, and not offering an opinion regarding the pharmacy benefits for these plans. I am offering no opinion on the cost of the consumers' or third-party purchasers' purchases for VCDs or the costs of such generic drugs under the pharmacy benefit.

III. PRICING OF HEALTH CARE SERVICES

A. Definitions

11. A discussion of the pricing of health care services in the U.S. first requires a foundation of clear terminology. For the purposes of this report and following the convention of the health policy and health economics scholarship, I first define and distinguish between several related, but different, entities: **price**, **charge**, **spending**, and **cost**. I define the components of price, namely the insurer component of the price and the patient component of the price (cost-sharing).

12. The **price** of a health care service is defined as the total paid amount per unit of service, which encompasses the insurer component and the patient component.[6] The price is typically determined in two main ways, based on the insurer. First, it is administratively set, in other words regulated, in public insurance programs, namely Medicare, which leaves no room for negotiation with health care providers. This is essentially a final offer to health care providers, who act as "price takers" in Medicare. Second, prices are determined through negotiation in commercial health insurance, in which commercial insurers and health care providers come together to bargain and agree on the prices per unit of service that the insurers will reimburse the providers. Details of how Medicare and commercial prices are set are explained below.

13. For patients with health insurance, the price of a health care service often comprises a portion that the insurer pays and a portion that the patient pays. The latter is generally described

[6] Association of American Medical Colleges (AAMC), "Price Transparency: Common Definitions" (https://www.aamc.org/system/files/c/2/450000-pricetran_commondefs.pdf).

as "cost-sharing" and can be implemented through a deductible, a co-insurance, or a copayment (copay). Another term that is often interchangeable with "cost-sharing" is the "out-of-pocket" spending for the patient, although the latter may also include the monthly premiums or enrollment costs to carry insurance, in addition to the cost-sharing at the point of care. To define the elements of cost-sharing, a deductible is a fixed amount that an insured patient must pay at the beginning of an insurance period (typically a year) before insurance benefits begin. Co-insurance is a fixed share or percentage of prices that the patient pays (it proportionally increases with the price). A copayment is a fixed dollar amount per unit of service that the patient pays.

14. In contrast to price, the **charge** of a service is the provider's asking price. The charge typically far exceeds the price, whether a price is administratively set or negotiated. Charges comes from the "chargemaster," a private document that providers have which lists the asking price of every service that a hospital or physician charges.[7] Literature and evidence from patient bills suggest that chargemaster amounts are often extremely high and not justified.[8] Notably, charges from a chargemaster do not reflect the negotiation between insurers and providers that in-network prices do. Nor do they reflect any administratively set price in the public domain, such as the Medicare prices also discussed above. Rather, chargemaster amounts are generally known to be unilaterally and solely determined by the provider.[9] While charges are rarely paid for patients who have health insurance, charges are commonly faced by uninsured or underinsured patients who do not have the benefit of insurers setting or negotiating a price on their behalf. In these cases, patients can be charged the full asking price of the provider or charged the remaining balance of a bill after a portion is paid by insurance (known as a balance

---

[7] AAMC, "Price Transparency: Common Definitions," *opt. cit.*

[8] B. Richman, M. Hall, and K. Schulman, "Overbilling and Informed Financial Consent--a Contractual Solution," *New England Journal of Medicine*, 367(5), 2012, pp. 396-397 at p. 396; E. Rosenthal, "After Surgery, Surprise $117,000 Medical Bill From Doctor He Didn't Know," *The New York Times*, September 20, 2014 (https://www.nytimes.com/2014/09/21/us/drive-by-doctoring-surprise-medical-bills.html); S. Kliff, "The Case of the $629 Band Aid—and What it Reveals About American Health Care," *Vox*, May 13, 2016 (https://www.vox.com/2016/5/13/11606760/emergency-facility-fees-american-health-care); S. Kliff, "He Went to an In-Network Emergency Room: He Still Ended Up with a $7,924 Bill," *Vox*, May 23, 2018 (https://www.vox.com/2018/5/23/17353284/emergency-room-doctor-out-of-network).

[9] G. Bai, and G. F. Anderson, "US Hospitals Are Still Using Chargemaster Markups to Maximize Revenues," *Health Affairs*, 35(9), 2016, pp. 1658-1664 at p. 1658.

bill). In considering the prospective spending for a medical monitoring program, it would be generally applicable to think about the **prices** per unit of component services as defined above for patients whose insurance will cover the clinical monitoring services (which includes the portion paid by the insurer and the patient cost-sharing as defined above).[10] However, for patients who are uninsured or whose insurance will not cover the clinical monitoring services, the provider **charge** may need to be considered as the operative price.

15. In contrast to the price and charge, health care **spending** is defined as the total dollars spent on health care services—in other words, the prices of services multiplied by the quantity of services. Of course, spending on one unit of a service would simply equal the price of the service. However, in most situations, spending is an aggregate concept that encompasses the prices and quantities of different health care services. For example, it is the correct terminology to describe total national or state resources that goes to health care services.

16. Finally, the term **cost** is commonly used in the lay press and colloquially to mean either price or spending, but from a technical standpoint, the cost of health care refers to the input costs of production, or the resources required to produce a service.[11] This includes facilities, machines, and human resources, in other words costs incurred by the provider in order to provide a health care service. Table 1 below succinctly summarizes the definitions of these four key concepts. For the purposes of this report, I will adhere to these definitions above and will use the terms **price** and **spending** most frequently in the remainder of the report.

[10] For the purposes of this report, Counsel has instructed me to think about both the insurer portion and patient portion in considering the unit price of a health care service.

[11] AAMC, "Price Transparency: Common Definitions," *opt. cit.*

TABLE 1
DEFINITION OF KEY TERMS

Key term	Brief definition in the context of health care services
Price	Paid amount per unit of service, including insurer and patient components
Charge	Provider's unilateral asking amount from the chargemaster; exceeds the price
Spending	Total dollars spent; prices of services multiplied by quantities of services
Cost	Cost of producing health care services, including facility and human inputs

B. Pricing of Medical and Procedural Services in the U.S. Health Care System

17. The prices of health care services are delineated according to a fee schedule used by public and private insurers (sometimes called "payers"), on which each service has a unique Current Procedural Terminology (CPT) code. The CPT coding system has long been used by health care providers and insurers across the country for claims processing and reimbursement of health care services, and serves as the foundation or skeleton for the nomenclature of health care services. Created over five decades ago, it is managed by the American Medical Association's CPT Editorial Panel and recognized by the U.S. Department of Health and Human Services as a national coding set for health care provider services.[12] It is a uniform, standardized coding system in which each service is denoted by a five-digit alpha-numeric or numeric code (for example, 99213 for a 15-minute office visit of an established patient).[13] This standardization is important because patients may receive care from different physician and hospitals, who in turn can treat patients with various types of health insurance. The coding system thus gives public and

[12] American Medical Association (AMA), "CPT® Overview and Code Approval" (https://www.ama-assn.org/practice-management/cpt/cpt-overview-and-code-approval).

[13] *Ibid*.

private insurers, providers, and policymakers a common language with which to use for claims submission, processing, and payment.

18. With each health care service designed through a CPT code, the pricing of services takes place in two stages. In stage 1, each service code receives an underlying valuation, quantified in relative value units (RVUs). RVUs come from the Resource-Based Relative Value Scale, a system that assigns a valuation (a number) on a uniform linear scale (from zero upward) to each physician service "based on the resources" required to produce and deliver that service—thus enabling different services to be compared to each other, hence the phrase "relative value." This uniform scale enabled medical services that differ substantially in nature, such as a surgery, an X-ray image, and a psychotherapy visit to be valued using an analogous, apples-to-apples metric. Importantly, RVUs are not dollars; rather, they are abstract units of "worth" or value that must be converted to dollars through an RVU conversion factor as described below.[14]

19. The Resource-Based Relative Value Scale was signed into law in 1989 and implemented by the federal Health Care Financing Administration on January 1, 1992.[15] It was created with the launch of the Medicare Physician Fee Schedule and remains the dominant system of valuation of physician services for public and private insurers in the U.S. today.[16] Today, the Centers for Medicare and Medicaid Services (CMS) is ultimately responsible for the valuations of physician services using the Resource-Based Relative Value Scale and publishes valuations on an annual basis. The American Medical Association's Relative Value Scale Update Committee, which is a multispecialty committee of about 32 or so members, many appointed by major

[14] Medicare Payment Advisory Commission (MedPAC), "Payment Basics: Physician and Other Health Professional Payment System," October 2020 (http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_20_physician_final_sec.pdf?sfvrsn=0); AMA, "2021 RVS Update Process" (https://www.ama-assn.org/system/files/2020-09/ruc-update-booklet.pdf).

[15] W. Hsiao, *et al.*, "Results and Impacts of the Resource-Based Relative Value Scale," *Medical Care*, 30(11 Suppl), 1992, pp. NS61-79 at p. NS61; W. Hsiao, *et al.*, "An Overview of the Development and Refinement of the Resource-Based Relative Value Scale," *Medical Care*, 30(11 Suppl), 1992, pp. NS1-12 at p. NS1; J. Levy, *et al.*, "Understanding the Medicare Fee Schedule and its Impact on Physicians Under the Final Rule," *Medical Care*, 30(11 Suppl), 1992, pp. NS80-94 at p. NS80.

[16] AMA, "RVS Update Committee (RUC)" (https://www.ama-assn.org/about/rvs-update-committee-ruc/rvs-update-committee-ruc).

national medical societies, provides CMS recommendations on how many RVUs to assign to any given physician service, including the ED evaluation and management services in this matter. CMS generally accepts the recommendations of the committee.[17]

20. Each physician service's total RVUs is comprised of three components: (1) RVUs for physician "work," (2) RVUs for "practice expense," and (3) RVUs for "professional liability insurance" or, historically, "malpractice" risk.[18] The amount of RVUs assigned to these three components are determined from survey data and other sources that the Relative Value Scale Update Committee reviews. Work RVUs reflect the amount or intensity of physician diagnostic or treatment effort that goes into a service (*e.g.*, a technically complex procedure will carry more work RVUs than an office visit). Practice expense RVUs aim to reflect the input costs of production such as tools, operating tables, scanners, and other resources.[19] These first two components of the RVU—work and practice expense—generally comprise the bulk of the total RVUs. Lastly, malpractice RVUs reflect the risk of litigation (*e.g.*, a high-risk procedure will carry more malpractice RVUs than an office visit).

21. For each service, its RVUs are converted into its price by multiplying the total number of RVUs by a RVU conversion factor. The RVU conversion factor is defined as a certain number of dollars per RVU. In 2021, for example, the RVU conversation factor in Medicare is $34.8931 per RVU. The federal Medicare program does not negotiate with providers on either the RVU assignments or the RVU conversion factor. In other words, Medicare has substantial purchasing power as a large payer (and legislative authority) to set the prices it is willing to pay. In turn,

---

[17] M. Laugesen, R. Wada, and E. Chen, "In Setting Doctors' Medicare Fees, CMS Almost Always Accepts the Relative Value Update Panel's Advice on Work Values," *Health Affairs,* 31(5), 2012, pp. 965-972; MedPac, "Report to the Congress: Medicare Payment Policy," March 13, 2020 (http://medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0).

[18] MedPAC, 2020, *opt. cit.*, United States Government Accountability Office, "Medicare Physician Fees: Geographic Adjustment Indices Are Valid in Design, but Data and Methods Need Refinement," Report to Congressional Committees, March 2005 (https://www.gao.gov/assets/gao-05-119.pdf); W. Hsiao, *et al.,*"Resource-Based Relative Values: An Overview," *JAMA*, 260(16), 1988, pp. 2347-2353; S. Maxwell, S. Zuckerman, R.A. Berenson, "Use of Physicians' Services Under Medicare's Resource-Based Payments," *New England Journal of Medicine*, 356(18), 2007, pp. 1853-1861.

[19] *Ibid.*

health care providers are "price takers;" if they choose to provide medical services to a Medicare beneficiary, they would be reimbursed at the traditional fee-for-service Medicare price.[20] Table 2 shows the number of RVUs in 2021 for several example services, and their resulting Medicare prices given the 2021 Medicare conversion factor. Other key details of the Medicare payment system for physician services are described by the MedPAC's overview of the payment system for physician and health professional services.[21]

TABLE 2
2021 RELATIVE VALUE UNITS (RVUS) AND MEDICARE PRICES FOR EXAMPLE SERVICES

Service (CPT Code)	Relative Value Units (RVUs) in Medicare				Medicare Conversion Factor (CF)	Medicare Price (RVUs x CF)
	Physician Work	Practice Expense	Professional Liability	Total RVUs		
Electrocardiogram (93010)	0.17	0.06	0.01	0.24	$34.89/RVU	$8.37
Mid-level office visits (99213)	1.30	1.25	0.10	2.65	$34.89/RVU	$92.47
High-level ED visit (99285)	4.00	0.75	0.43	5.18	$34.89/RVU	$180.75

Notes: physician work RVUs, practice expense RVUs, professional liability insurance RVUs, the Medicare conversion factor, and the Medicare price are all public data reported in the Medicare Physician Fee Schedule by the Centers for Medicare and Medicaid Services.[22]

[20] Even a physician or hospital who treats a Medicare beneficiary in Medicare Advantage (a private Medicare plan) as an out-of-network provider must, by law, accept the traditional fee-for-service Medicare price as payment in full. The relevance of provider network status for prices in commercial insurance is discussed in section C below.

[21] MedPAC, 2020, *opt. cit.*

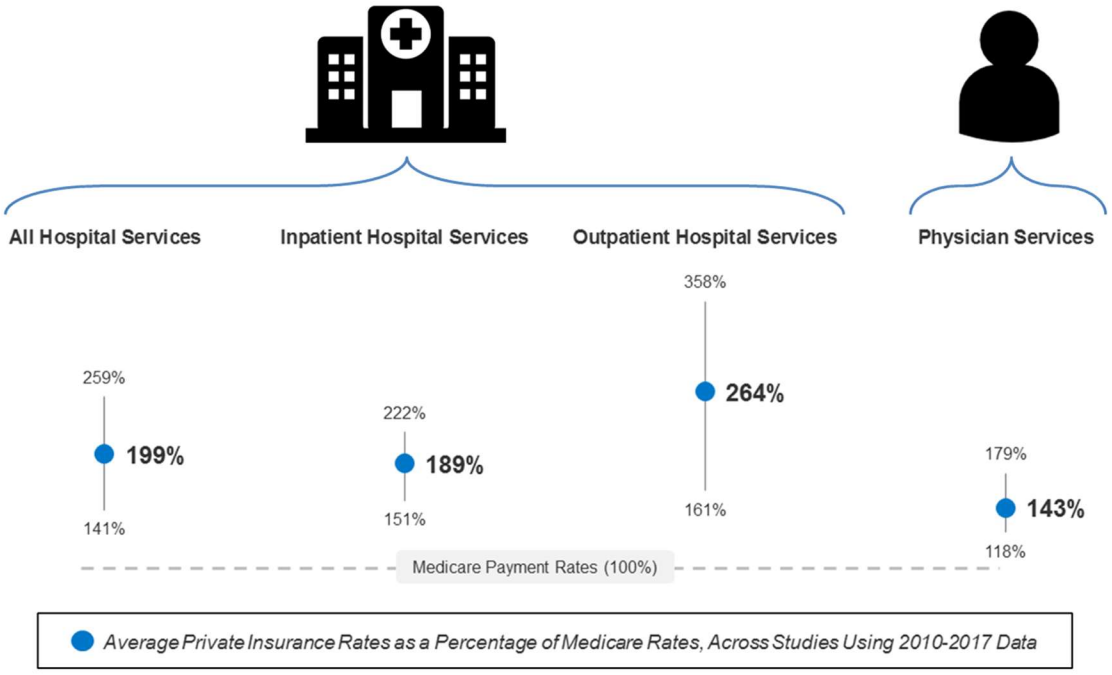
[22] Centers for Medicare and Medicaid Services (CMS), "Medicare Physician Fee Schedule Lookup Tool" (https://www.cms.gov/medicare/physician-fee-schedule/search/overview). To find RVUs and the Medicare Conversion Factor, type the CPT codes into the "HCPCS Code" field" and under "MAC Option," select "National Payment Amount."

22. Commercial insurers generally use the same underlying RVU valuations as those used by Medicare. However, unlike the national RVU conversion factor that Medicare administratively sets and publishes each year, the RVU conversion factor that determines a commercial insurer's price is typically negotiated between the insurer and individual provider groups in their insurance networks. Moreover, this is typically private information. However, a large research evidence base has revealed that U.S. commercial insurer prices for physician services are 43% higher (a ratio of 1.43), on average, compared to Medicare prices for the same service.[23] U.S. commercial insurer prices for hospital outpatient services (often called "HOPD," "OPD," or "Outpatient Hospital Services" as in the figure below) are on average 164% higher (a ratio of 2.64) than Medicare prices.[24] An example of a hospital outpatient service is an emergency department visit. The key figure from the Lopez, *et al.,* meta-analysis (2020) cited here is shown below as Figure 1.

[23] E. Lopez, *et al.*, "How Much More Than Medicare Do Private Insurers Pay? A Review of the Literature," Kaiser Family Foundation Issue Brief, April 15, 2020 (https://www.kff.org/report-section/how-much-more-than-medicare-do-private-insurers-pay-a-review-of-the-literature-issue-brief/). See also the 19 individual studies that comprised this meta-analysis.

[24] *Ibid.*

FIGURE 1
COMMERCIAL VS. MEDICARE PRICES IN THE U.S.—A SUMMARY OF THE EVIDENCE



SOURCE: KFF analysis of 19 published studies comparing private insurance and Medicare payments to providers. Because some studies analyze payments to providers in multiple service categories, the number of studies across all categories is greater than 19.

KFF
HENRY J KAISER FAMILY FOUNDATION

23. The underlying RVUs for each service are typically the same in commercial insurance as in Medicare. However, the average commercial insurer RVU conversion factor for physician services has been roughly $49.90 per RVU ($34.8931 x 1.43 = $49.8971), according to the 1.43 ratio in Lopez, *et al.* (2020). The commercial insurer RVU conversation factor for hospital outpatient services has averaged $92.12 per RVU ($34.8931 x 2.64 = $92.1178), using the 2.64 ratio in Lopez, *et al.* (2020). In other words, price differences between Medicare and commercial insurers are generally due to differences in the conversion factor, rather than differences in the underlying RVUs of services. Building on this fact, Table 3 estimates average commercial prices in the U.S. for the same example services shown in Table 2. While this Table shows a national

average estimate using the conversion factors above, commercial prices for a given service vary substantially by geography due to differences in provider market power relative to insurers.[25]

TABLE 3
ESTIMATED 2021 AVERAGE U.S. COMMERCIAL PRICES FOR THE SAME EXAMPLE SERVICES

Service (CPT Code)	Relative Value Units (RVUs) in Medicare				Commercial Insurer Conversion Factor (CF)	Commercial Insurer Price (RVUs x CF)
	Physician Work	Practice Expense	Professional Liability	Total RVUs		
Electrocardiogram (93010)	0.17	0.06	0.01	0.24	$49.90/RVU	$11.98
Mid-level office visit (99213)	1.30	1.25	0.10	2.65	$49.90/RVU	$132.23
High-level ED visit (99285)	4.00	0.75	0.43	5.18	$92.12/RVU	$477.17

Notes: physician work RVUs, practice expense RVUs, and professional liability insurance RVUs are public data reported in the Medicare Physician Fee Schedule by the Centers for Medicare and Medicaid Services.[26] Given the data in Lopez, *et al.* (2020) described in the text above, I used the commercial-to-Medicare price ratio of 1.43 to derive the conversion factor of $49.90/RVU for the electrocardiogram and mid-level office visit, as these services can be delivered in a freestanding physician office. I used the commercial-to-Medicare price ratio of 2.64 for the ED visit, given that ED visits are most often delivered in the facility setting.

24. Outside of Medicare (which covers about 61 million people or approximately 14% of the U.S. population)[27] and commercial insurance (which covers over half of the U.S. population), a large portion of the nation's population—over 72.5 million Americans—receive health insurance coverage through Medicaid, which is a joint federal-state health insurance program that insures a large share of the nation's children, pregnant women, low-income adults, and disabled persons.[28] Every state administers its own Medicaid program, supported by matching funds from the federal

[25] C. White and C. Whaley, "Prices Paid to Hospitals by Private Health Plans Are High Relative to Medicare and Vary Widely: Findings from an Employer-Led Transparency Initiative," *RAND Corporation Research Reports*, 2019, pp. 18-31 (https://www.rand.org/pubs/research_reports/RR3033.html).

[26] CMS, "Medicare Physician Fee Schedule Lookup Tool," *op. cit*.

[27] CMS, "Total Medicare Enrollment: Total, Original Medicare, and Medicare Advantage and Other Health Plan Enrollment, Calendar Years 2014-2019" (https://www.cms.gov/files/document/2019cpsmdcrenrollab1.pdf).

[28] Medicaid.gov, "Eligibility" (https://www.medicaid.gov/medicaid/eligibility/index.html).

government. States vary in the design of their Medicaid programs, including prices. In general, Medicaid prices are lower than Medicare prices. On average, using 2016 data, it was estimated that Medicaid prices nationwide are approximately 72% of Medicare prices, though beneath this average is sizeable heterogeneity by state.[29] For example, Florida Medicaid prices were 56% of Medicare levels, while Virginia Medicaid prices were 92% of Medicare levels.

25. Lastly, about 2% of the U.S. population receive health insurance through other federal public programs, notably the Veterans Administration (VA) for veterans, Tricare for the military and families, and the Indian Health Service (IHS) for Native American populations. In general, these public programs pay health care providers Medicare prices.[30]

C. Pricing of Laboratory Services in the U.S. Health Care System

26. Before 2018, Medicare administratively set prices of laboratory tests based on the historical amounts charged by laboratory providers and capped them legislatively at certain levels.[31] This resulted in the Medicare Clinical Laboratory Fee Schedule. Congress first set limits on prices called national limitation amounts in 1986, and actual Medicare prices were the lesser of (1) a laboratory's charges, (2) the local fee schedule amount and (3) the national limitation amount.[32] Empirically, the national limitation amount is often the paid amount. For example, an Office of Inspector General report found that 89% of Medicare laboratory tests in 2007 were

---

[29] Kaiser Family Foundation, "Medicaid-to-Medicare Fee Index" (https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index)

[30] Department of Veterans Affairs, "Veterans Community Care Program, Final Rule," *Federal Register*, 84(108), 2019, pp. 26278-26310; 10 U.S. Code, Chapter 55 – Medical and Dental Care, Section 1079, "Contracts for medical care for spouses and children: plans," (https://uscode.house.gov/view.xhtml?path=/prelim@title10/subtitleA/part2/chapter55&edition=prelim); Indian Health Service (IHS), CMS, Health and Human Services (HHS), "Section 506 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Limitation on Charges for Services Furnished by Medicare Participating Inpatient Hospitals to Individuals Eligible for Care Purchased by Indian Health Programs, Final Rule," *Federal Register*, 72(106), 2007, pp. 30706-30711.

[31] CMS, "Medicare Will Use Private Payor Prices to Set Payment Rates for Clinical Diagnostic Laboratory Tests Starting in 2018," CMS press release, June 17, 2016 (https://www.cms.gov/newsroom/press-releases/medicare-will-use-private-payor-prices-set-payment-rates-clinical-diagnostic-laboratory-tests).

[32] Department of Health and Human Services (HHS), "Medicare Reimbursement for Outpatient Laboratory Services," Office of Inspector General Report, March 1989 (https://oig.hhs.gov/oei/reports/oai-04-88-01080.pdf).

paid at the national limitation amount.[33] This national limitation amount was initially set at 115% of the median of all local fee schedule amounts.[34] However, Congress has periodically lowered this cap to create savings. Since 1998, national limitation amounts have been set at 74% of the median of all local fee schedule amounts (100% of the median for new tests performed on or after 2001).[35] Before 2018, the Medicare Clinical Laboratory Fee Schedule prices had exceeded commercial prices in part because Medicare did not adjust prices to reflect modern efficiencies in laboratory testing, including the changes in technology (lower input costs) or market conditions.

27. Starting in 2018, however, Medicare based laboratory pricing on commercial insurer prices. This was a major change in the way that the federal government pays for laboratory tests, and it was codified in the Protecting Access to Medicare Act of 2014 (PAMA). PAMA required laboratories to report the prices they receive from private insurers, which Medicare then uses to establish its own prices.[36] In January 2018, Medicare began paying for laboratory tests using the volume-weighted median of all reported commercial insurer prices collected from laboratories during the period between January and June 2016.[37] These commercial insurer-based prices were not subject to any adjustments (*e.g.*, for geography, annual updates, or budget neutrality requirements). Rather, they will only be updated when Medicare collects another round of data.[38] PAMA also created a new category of laboratory tests called "advanced diagnostic laboratory tests," which includes more complex molecular and genetic tests; these have separate reporting

---

[33] HHS, "Variation in the Clinical Laboratory Fee Schedule," Office of Inspector General Report, July 2009 (https://oig.hhs.gov/oei/reports/oei-05-08-00400.pdf).

[34] MedPAC, "Chapter 9: Mandated report: Assessing the impact of recent changes to Medicare's clinical laboratory fee schedule payment rates," Report to the Congress: Medicare and the Health Care Delivery System, June 2021 (http://www.medpac.gov/docs/default-source/default-document-library/jun21_medpac_report_to_congress_sec.pdf?sfvrsn=0).

[35] *Ibid.*

[36] CMS, "Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System," September 22, 2017, pp. 1-11 at p. 1 (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf).

[37] *Ibid.*, p. 2.

[38] S. Murrin, Department of Health and Human Services, "Changing How Medicare Pays for Clinical Diagnostic Laboratory Tests: An Update on CMS's Progress," Update from the Deputy Inspector General for Evaluation and Inspections, September 2016, pp. 1-16 at p. 2 (https://oig.hhs.gov/oei/reports/oei-09-16-00100.pdf).

and payment requirements, and are also more expensive than the more routine tests.[39] The full impact of the changes in prices under PAMA from the first round of data reporting was phased in over the period 2018-2022, during which the impact in any one year would be capped at a given level. From 2018 through 2020, payment rate reductions were capped at 10 percent per year. In 2021, they were capped at 0 percent (therefore, no reductions). In 2022, they are scheduled to be capped at 15 percent. Any payment rate increases under the PAMA, which were also possible based on the laboratory reported commercial insurer prices, were implemented immediately in 2018.[40]

D. Variations in Prices Within Insurers

28. Not only do the prices of health care services vary *between* insurers, such as the major public insurer Medicare and commercial insurers as Section B above illustrated, the price of a given service can also differ in important ways *within* a given insurer. This section describes two notable ways that prices vary within insurers: differences across sites of care, and differences by in-network or out-of-network status of the health care provider in a person's insurance plan.

29. Prices vary based on the site of care. In an independent, physician-owned practice setting (most commonly a freestanding outpatient physician office in the community), public and private insurers will reimburse the provider a single, aggregate fee for a given health care service. There is no distinction between a facility component or a professional component of the fee. However, when a service is delivered in a facility setting, frequently the "hospital outpatient department" (often referred to as the "HOPD" or "OPD") setting, it garners two fees—a "facility fee" for the hospital and a "professional fee" for the physician. Although the physician fee in the facility setting is typically lower than the single fee in the freestanding physician office setting, the sum of the facility fee and professional fee in the facility setting generally exceeds the latter, typically

[39] *Ibid.*, p. 13.

[40] MedPAC, 2021, *opt. cit.*

by a substantial margin.[41] Table 4 below from MedPAC's June 2013 Report to the Congress provides a classic example of this difference in Medicare price by site of care.[42] In this example using a mid-level office visit (CPT code 99213), the Medicare price is $72.50 in the freestanding physician office setting, but $123.38 in the hospital outpatient department setting ($73.68 for the facility fee, and $49.70 for the professional fee). This type of gap is analogous for essentially all services that can be delivered in a freestanding office setting and a facility setting. Of note, when a freestanding physician office is acquired by a hospital, as is common through vertical consolidation, the physician's site of care may acutely change to the facility setting.[43] The result is that a given medical service previously delivered in a freestanding physician office, now delivered in the facility setting, becomes higher priced even if the actual physician, the patient, and the service does not change.[44]

TABLE 4
MEDICARE PRICE FOR A MID-LEVEL EVALUATION AND MANAGEMENT OFFICE VISIT IN A FREESTANDING PHYSICIAN PRACTICE VS. HOSPITAL OUTPATIENT DEPARTMENT (OPD)

	Service provided in freestanding physician practice*	Service provided in OPD		
		Physician facility rate*	OPPS rate	Total, OPD rate
Program payment	$58.00	$39.76	$58.94	$98.70
Beneficiary cost sharing	14.50	9.94	14.74	24.68
Total payment	72.50	49.70	73.68	123.38

Note: E&M (evaluation and management), OPD (hospital outpatient department), OPPS (outpatient prospective payment system). The Current Procedural Terminology code for this visit is 99213.
*Paid under the Medicare physician fee schedule.
Source: MedPAC analysis of payment rates in the 2013 physician fee schedule and OPPS.

Note: The CPT code for a mid-level (15-minute) evaluation and management office visit for an established patient is 99213. This is one of the most common medical services in the U.S.

[41] MedPAC, "Report to the Congress: Medicare and the Health Care Delivery System," June 2013, pp. 3-281 at pp. 31-32 (http://medpac.gov/docs/default-source/reports/jun13_entirereport.pdf).

[42] *Ibid.*

[43] In some cases, the physician's office may not need to physically relocate into the facility setting. The change in ownership or affiliation may be sufficient to qualify the practice as facility-based.

[44] Z. Song, *et al.*, "Medicare Fee Cuts and Cardiologist-Hospital Integration," *JAMA Internal Medicine*, 175(7), 2015, pp. 1229-1231; MedPAC, 2013, *op. cit*.

30. Second, prices differ by whether the health care provider is in-network or out-of-network for the patient's insurance plan. In commercial health insurance, physicians and hospitals can command higher commercial prices when they deliver care as out-of-network providers than when they deliver care as in-network providers.[45] This markup can be substantial for patients and families.[46] Why do networks exist? Health insurance companies create provider networks to enhance their bargaining power relative to physicians and hospitals and to steer their enrollees to lower cost or higher quality providers.[47] Enrollees are typically encouraged to go to in-network physicians and hospitals with incentives such as lower cost-sharing. Enrollees are frequently discouraged from going to out-of-network physicians and hospitals through the disincentive of higher cost-sharing. Thus, by negotiating for in-network prices with insurers, providers gain easier access to a group of in-network enrollees—who are potential patients—upon agreeing to be included in an insurance plan's network. By staying out of an insurance plan's network,

---

[45] See, for example, Z. Cooper, *et al.*, "Out-Of-Network Billing And Negotiated Payments For Hospital-Based Physicians," *Health Affairs*, 39(1), 2020, pp. 24-32; Z. Cooper and F. Morton, "Out-of-Network Emergency-Physician Bills—An Unwelcome Surprise," *New England Journal of Medicine*, 375(20), 2016, pp. 1915-1918; N. Benson and Z. Song, "Prices and Cost Sharing for Psychotherapy In Network Versus Out Of Network in the United States," *Health Affairs*, 39(7), 2020, pp. 1210-1218; W. Johnson, *et al.*, "Out-of-Network Spending: Why Growing Attention Is Focused on a Small Share of Medical Spending," *Health Affairs Blog*, June 2, 2020 (https://www.healthaffairs.org/do/10.1377/hblog20200601.723677/full/); Z. Song, *et al.*, "Out-of-Network Spending on Behavioral Health, 2008–2016," *Journal of General Internal Medicine*, 36(1), 2020, pp. 232-234; A.P. Sen, *et al.*, "Frequency and Costs of Out-of-Network Bills for Outpatient Laboratory Services Among Privately Insured Patients," *JAMA Internal Medicine*, 181(6), 2021, pp. 834-841.

[46] Z. Cooper, F. Morton, and N. Shekita, "Surprise! Out-of-Network Billing for Emergency Care in the United States," *Journal of Political Economy*, 128(9), 2020, pp. 3626-3677; C. Garmon and B. Chartock, "One In Five Inpatient Emergency Department Cases May Lead To Surprise Bills," *Health Affairs*, 36(1), 2017, pp. 177-181; E. Rosenthal, "How the High Cost of Medical Care Is Affecting Americans," *The New York Times*, December 18, 2014 (https://www.nytimes.com/interactive/2014/12/18/health/cost-of-health-care-poll.html); E. Rosenthal, "Insured, but Not Covered." *The New York Times*, February 7, 2015 (https://www.nytimes.com/2015/02/08/sunday-review/insured-but-not-covered.html); T. Bernard, "Out of Network, Not by Choice, and Facing Huge Health Bills," *The New York Times*, October 18, 2013 (https://www.nytimes.com/2013/10/19/your-money/out-of-network-not-by-choice-and-facing-huge-health-bills.html); Massachusetts Health Policy Commission, "Out-of-network Billing in Massachusetts," November 1, 2017 (https://www.mass.gov/doc/presentation-out-of-network-billing-in-massachusetts/download); AHIP Center for Policy and Research, "Charges Billed by Out-of-Network Providers: Implications for Affordability," September 2015 (https://www.ahip.org/wp-content/uploads/2015/09/OON_Report_11.3.16.pdf).

[47] K. Ho and R. Lee, "Equilibrium Provider Networks: Bargaining and Exclusion in Health Care Markets," *American Economic Review*, 109(2), 2019, pp. 473-522 at p. 473; K. Ho and R. Lee, "Narrow Medical Provider Networks: Welfare Implications and Approaches to Market Design," *More Fair by Design: Design Responses to Inequality*, Vol. IV. Eds. S. Kominers and A. Teytelboym. Oxford: Oxford University Press, 2016 pp. 1-11.

physicians and hospitals may lose access to those patients. However, providers may also decide to stay out of network for strategic reasons. If physicians, hospitals, or other providers (such as independent laboratories) reject the in-network price or simply do not want to be in an insurance plan's network, they can deliver care outside of any insurer's network and bill a higher charge (since they are not bound by the negotiated in-network price). This, of course, could lead to a loss of potential customers if patients find the out-of-network charge too prohibitive (assuming the forthcoming charge is disclosed to them before they consume the service). However, if a provider is not concerned about losing patients and has the market power to attract patients, such as through reputation or being the sole provider in a certain geography and thus operating without market competition, then in a purely economic sense the revenue-maximizing strategy could be to stay out-of-network for all commercial insurers. Table 5 below, adapted from my published analysis using 2016 data within a large commercial and Medicare claims database, shows the Medicare price for the same 3 example services in Tables 2 and 3 above compared to the average in-network and out-of-network commercial price.[48] Across these examples, the out-of-network prices are substantially higher than the in-network prices.

[48] Z. Song, "The Pricing of Care Under Medicare for All: Implications and Policy Choices," *opt. cit*.

TABLE 5
MEDICARE PRICES VS. IN-NETWORK AND OUT-OF-NETWORK COMMERCIAL PRICES, 2016

Physician service (CPT code)	Medicare Price	Commercial Insurer Price			
		In-Network		Out-of-Network	
		Price	Ratio to Medicare	Price	Ratio to Medicare
Electrocardiogram (93010)	$9	$17	1.9	$28	3.3
Mid-level office visit (99213)	$73	$80	1.1	$100	1.4
High-level ED visit (99285)	$175	$442	2.5	$686	3.9

Notes: Adapted from Z. Song, "The Pricing of Care Under Medicare for All: Implications and Policy Choices," *Journal of the American Medical Association*, 322(5), 2019, pp. 395-396. Please note that the commercial prices reported in this study differ from the commercial prices estimated in Table 3 for these example services because this study calculated the prices in a large, convenience sample of commercially insured populations in the 2016 IBM Marketscan commercial claims database, one of the nation's largest commercial insurer databases, whereas prices in Table 3 were estimated using the conversion factors derived from the Lopez, *et al.* (2020) meta-analysis. Despite the difference in prices, these commercial prices across the two Tables are all consistently greater than Medicare prices, and their gap with respect to Medicare prices are of a similar magnitude.

31. In summary, the price of a health care service differs *between* insurers, ranging from Medicaid prices, to Medicare prices, to commercial insurer prices. This is largely explained by Medicaid and Medicare being able to administratively set their prices without negotiation; in contrast, commercial insurers negotiate with providers over prices, which renders the relative difference in market power between the parties important in determining prices. Prices also differ *within* insurers, based on the site of care and whether a provider is in-network or out-of-network with respect to an individual's insurance plan. Site of care is important for prices because some sites are paid a single aggregate fee, whereas other sites are paid a combination of a facility fee for the facility and a profesional fee for the physician. Provider network status matters for prices because in-network physicians and hospitals negotiate in-network prices in exchange for easier access by a population of insured individuals, whereas out-of-network providers are not bound by in-network negotiated prices and can garner higher prices. These basic tenets of pricing offer the foundations for a common methodology to estimate health care spending from a medical

monitoring program. They also convey the fact that a population's insurer mix, site of care, and network status of providers are relevant parameters to consider in estimating spending.

IV. COMMON METHODOLOGY FOR ESTIMATING SPENDING ON MEDICAL MONITORING

A. Medical Services in a Monitoring Program

32. The first step toward estimating the health care spending associated with a monitoring program is to define the services in the monitoring program and the frequency with which they will be used in the monitoring program for a member of the monitoring class. For the purposes of this report, I assume in this section that the foundation of such a potential monitoring program could begin with the following services: a urinalysis on an annual basis, a complete blood count on an annual basis, an evaluation and management (office visit) on an annual basis, a low-dose computed tomography (CT) chest imaging test on an annual basis, an upper endoscopy every five years, and a screening colonoscopy every five years. I consider these an example of an initial core set of medical services that patients with an increased risk of cancer could benefit from, to which additional services that are deemed appropriate for this class of patients may be added.

33. The second step toward estimating spending is to determine the price of each service that would apply to different insurers. Table 6 below shows the published 2021 Medicare prices for the above services in the non-facility setting, alongside the estimated national average Medicaid prices and estimated national average commercial prices. To further specify a concrete example for each service, I selected a common CPT code for services that have multiple variations, each with its own multiple CPT code. For example, there are approximately 10 different types of urinalysis tests, each with its own CPT code; for the purposes of this report, I selected the fairly common CPT code 81001, which the 2021 Medicare Clinical Diagnostic Laboratory Fee Schedule defines as a "manual urinalysis test with examination using microscope, automated."

34. For laboratory services, for the purposes of this illustration, I assumed that Medicare prices published under the PAMA would equal commercial prices, given that Medicare prices are determined by the commercial prices reported to federal regulators as specified by PAMA.

35. For medical services, I used the national average ratio of commercial-to-Medicare prices of 1.43 for physician services from Figure 1 to estimate the commercial prices. This ratio may generate, on average, a *conservative* estimate of commercial prices because services delivered in hospital outpatient departments, as discussed above, would likely garner facility fees that adhere to the 2.64 average ratio of commercial-to-Medicare prices from Figure 1. Notably, endoscopies, colonoscopies, CT chest imaging, laboratory tests, and even office visits frequently occur in hospital outpatient departments. It would be possible to model the share of services delivered in different sites of care, including the freestanding office and hospital outpatient departments. It would also be straightforward to analogously calculate the estimated commercial prices in the hospital outpatient department setting using a higher RVU conversion factor (Figure 1).

36. Alternatively, commercial prices, rather than being estimated using a conversion factor informed by the peer-reviewed research evidence base, could be directly calculated using a large commercial insurer claims database that contains unit prices at the service level. Examples of such commercial insurer claims database databases include the Health Care Cost Institute data, the IBM Marketscan Commercial Claims and Encounters database, and the FairHealth database.

37. All Medicaid prices for services in the table were calculated using the 0.72 Medicaid-to-Medicare national average price ratio. Depending on the locations of Medicaid members in the class, more geographically granular estimates of Medicaid prices can be calculated using state-specific Medicaid-to-Medicare price ratios.[49] In theory, Medicaid claims data could also be used to directly calculate Medicaid prices, although data availability can be more challenging and the quality of the claims data may vary across states.

38. If an individual is uninsured, the patient would not fall into any of the three major insured population segments shown in the table. The uninsured patient could face provider charges (from the chargemaster) billed directly to the patient or charges net of any provider discounts for an uninsured person. Although data on provider charges are less systematically available, it would be possible to model the markup of provider charges from prices using published data.

[49] Kaiser Family Foundation, "Medicaid-to-Medicare Fee Index" *op. cit.*

TABLE 6
2021 MEDICARE PRICES AND ESTIMATED MEDICAID AND COMMERCIAL PRICES

Service (CPT code)	Medicare Price ($)	Medicaid Price ($)	Commercial Price ($)
Urinalysis (81001)	3.17	2.28	3.17
Complete blood count (85025)	7.77	5.59	7.77
Office visit (99214)	131.20	94.46	187.62
Low-dose chest CT scan (71271)[50]	150.74	108.53	215.56
Upper endoscopy (43235)	311.60	224.35	445.59
Screening colonoscopy (G0121)[51]	357.31	257.26	510.95

Notes: Medicare prices for physician services are obtained from the Medicare Physician Fee Schedule, 2021 national average payment amounts for the non-facility setting (*i.e.*, freestanding physician office setting).[52] Medicare prices for laboratory services are obtained from the Clinical Laboratory Fee Schedule, 2021 quarter 1 posting.[53] Medicaid prices are estimated by using the national average Medicaid-to-Medicare physician fee ratio of 0.72.[54] Commercial prices are similarly estimated at the national average level by applying the ratio of 1.43 to Medicare prices. The specific CPT codes were selected because they are common CPTs in the category of services; they are used for illustrative purposes here. Prices reflect the sum of both the insurer share and patient cost-sharing per unit of a service.

[50] CMS, "Medicare HETS 270/271 - Reminder - HETS HCPCS Code Change Effective January 31, 2021," (https://www.cms.gov/research-statistics-data-and-systemscms-information-technologyhetshelpmcare-notification-archive/medicare-hets-270271-reminder-hets-hcpcs-code-change-effective-january-31-2021). American College of Radiology, "Low-Dose CT Lung Cancer Screening FAQ" (https://www.acr.org/Clinical-Resources/Lung-Cancer-Screening-Resources/FAQ).

[51] CMS, "Changes to Claims Processing Instructions for Colorectal Cancer Screening Services," December 17, 2001, (https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1735B3.pdf). American Society of Gastroenterology, "2018 CPT Changes" (https://www.asge.org/docs/default-source/coding/colonoscopy_2018-coding-sheet.pdf). American Gastroenterological Association, "What's the right code to use for screening colonoscopy?" (https://gastro.org/practice-guidance/reimbursement/coding-faq-screening-colonoscopy/).

[52] CMS, "Medicare Physician Fee Schedule Lookup Tool," *op. cit*.

[53] CMS, "Clinical Laboratory Fee Schedule Files" (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Clinical-Laboratory-Fee-Schedule-Files).

[54] Kaiser Family Foundation, "Medicaid-to-Medicare Fee Index," *op. cit*.; E. Lopez, *et al.*, *op. cit.*

B. Composition of the Patient Population in Monitoring

39. The next step toward estimating spending for a monitoring program is to determine or estimate the size and composition of the patient population undergoing monitoring. This includes determining the insurer mix, site of care composition, and network status of the providers for the patient population. In addition, projecting future health care use requires assumptions about life expectancy and the development of medical conditions (e.g. cancer and other acute and chronic diseases) that may render the monitoring program less appropriate clinically. The prices in Table 6 provide a sense of spending in the initial years of a monitoring program, when the defined class of individuals would be more likely to be stable in its composition. To estimate spending during the remaining life cycle of the class of individuals, additional assumptions or parameters such as life expectancy (*e.g.*, for patients with hypertension or congestive heart failure, as these are key diagnosis that would more likely be clinical indications for taking valsartan) would be needed.

40. As the time horizon of estimation lengthens, prices may also evolve due to regulation or market forces. The federally set Medicare prices have tended to be fairly stable in recent years. In constrast, commercial prices have grown rather quickly, in part due to continued consolidation among providers, both horizontal consolidation (hospitals with hospitals or physician groups with physician groups) and vertical consolidation (hospitals acquiring physicians).[55] After adjusting for inflation, 75% of the growth in commercial prices nationwide from 2014 to 2018 were explained by growth in prices, as opposed to growth in the quantities or volume of care.[56] Therefore, estimating spending on a monitoring program may reasonably include assumptions about the growth rate of commercial prices over time.

---

[55] MedPac, "Report to the Congress: Medicare Payment Policy," March 13, 2020 (http://medpac.gov/docs/default-source/reports/mar20_entirereport_sec.pdf?sfvrsn=0); R. Abelson, "When Hospitals Merge to Save Money, Patients Often Pay More," *New York Times*, November 18, 2018 (https://www.nytimes.com/2018/11/14/health/hospital-mergers-health-care-spending.html); K. Schwartz, E. Lopez, M. Rae, and T. Newman, "What We Know About Provider Consolidation," September 2, 2020 (https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation/); L. Dafny, K. Ho, and R. Lee, "The Price Effects of Cross-Market Hospital Mergers," National Bureau of Economic Research Working Paper 22106, October 2018 (https://doi.org/10.3386/w22106).

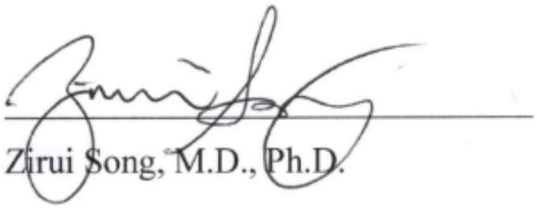
[56] Health Care Cost Institute, "HCCI's Health Care Cost and Utilization Reports," February 2020 (https://healthcostinstitute.org/annual-reports/2020-02-13-18-20-19)

41. Over longer time horizons, insurance switching would also be more likely, namely people on commercial insurance before age 65 who age into Medicare at age 65. Consistent with the descriptive data shown in Table 5, additional empirical evidence has demonstrated that entering Medicare at age 65 reduces health care spending for outpatient services by about 30%, driven by a reduction in prices at the age 65 threshold from commercial down to Medicare levels, without significant changes in overall utilization.[57] Therefore, given the age distribution of the class members and their rate of entry into Medicare from commercial insurance at age 65, estimates of spending on a monitoring program may also reasonably take into account the reduction in prices from commercial to Medicare levels as individuals enter Medicare.

C. Calculating Spending

42. In the class of patients in this case, the presumptive spending on a medical monitoring program can be calculated as the prices of health care services multiplied by the quantities of services determined to be in the monitoring program, applied to a population of people with a given health insurance mix, shares of services obtained at different sites of care, and shares of services delivered by in-network vs. out-of-network providers. Such a methodology would also be able to incorporate factors such as the expected number of years in the monitoring program, and rate of attrition from the monitoring program, and the contribution of market forces such as price inflation due to provider consolidation. Additional factors that affect prices or quantities of care may also be incorporated. The methodology described above would be applied in a common manner to all clinical services deemed to be in the monitoring program.

[57] J. Wallace and Z. Song, "Traditional Medicare Versus Private Insurance: How Spending, Volume, and Price Change at Age Sixty-Five," *Health Affairs*, 35(5), 2016, pp. 864-872.



Zirui Song, M.D., Ph.D.

November 10, 2021